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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,951	10/04/2004	Gerardo Perez-Camargo	115808-509	3093

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K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
12/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,951	PEREZ-CAMARGO ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,45,48-52 and 57-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35, 45, 48-52 and 57-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/remarks and amended claims all filed on 08/20/09 is acknowledged.

Claims 1-34, 36-44, 46-47, 53-56 and 65-68 have been cancelled.

Claims 35, 45, 48-52 and 57-64 are pending in this application and claims **35, 45, 48-52 and 57-64** will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3 Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation , acidifier which makes the claim indefinite. It is not clear which acidifier is utilized lactic acid or citric acid, the metes and bounds of claim is not defined. Claim 35 recite the limitation "fish oil" it is not clear which component is the applicant referring to, fish oil comprises EPA, DHA and other components. Specific recitation of components is requested.

Claims 45 and 57 recite the limitation "wherein the component has fatty acid profile selected to improve intestinal absorption; makes the claim indefinite. It is not clear which component is the Applicant referring to. There is no antecedent basis to claim. It is not clear how an acidifier can improve, maintain or promote cat's lipid absorption capacity and in turn improve or maintain absorption of vitamin E.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 35, 45, 48-52 and 57-64 are rejected 35 U.S.C. 103(a) as being unpatentable over (USP 6,471,999) in view of (USP 6,524,619) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease, Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS), (USP 6,228,367), (USP 6,610,007) and (W0 01/62280, presented in IDS).

'999 teach a pet milk powder as nutritional milk those results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces

gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, **taurine (a liver function promoter),** arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

'999 teaches that a protein source of whey protein and further supplemented with **taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40)**. (Lactic acid reads on pancreatic function promoter, therefore, it is obvious that an acidifier such as lactic acid produced by probiotics help in improving intestinal balance, it is to be noted that probiotics are known to produce lactic acid and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

'999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).

'999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends on factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), **vitamins,** minerals, and soybean oil, and adding water to provide nutritional supplement to **dogs and puppies or cats**. '999 teaches that a protein source of whey protein and further supplemented with taurine and a **probiotic micro-organism** which beneficially effects the host by improving its intestinal microbial

balance, such as lactic acid (col. 3, lines 25-40). '999 teach omega fatty acids such as **soybean oil** (It is to be noted that fish oil is known in the art to comprise omega fatty acids such as EPA and DHA ,see USP 6,608,223) and in Examples 1-2 (col. 3, lines 15-20). Soybean oil and vitamin has been shown to be at 1.7 percent by weight and 0.4% by weight respectively in Example 1 in column 4. The amount of soybean oil (which comprises omega fatty acid reads on a fatty acid with profile as claimed in instant claim 45) is within the claimed range of between about 0.1% to 20%.

The references disclosed above do not teach correlation of taurine with lipid absorption and correlation of lipid absorption with vitamin E levels.

"619 teaches taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (See the entire articles of record).

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by '999 in order to help in lipid absorption motivated by the teachings of '619 and would expect improvement in vitamin E absorption in light of the teachings of Simpson et al. which teaches that vitamin E deficiency occurs due to defect in lipid absorption.

It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as taurine to obtain best possible results by doing experimental manipulations because '999 teaches soybean oil (reads on both liver function promoter and intestinal function promoter as taught in instant specification) and vitamins in 1.7% and 0.4% amount (claimed as liver function promoter in instant specification), as such it would have been within the purview of a skilled artisan to optimize the amount of the claimed liver function promoter, taurine to obtain best possible results and come to the claimed invention.

The teachings of references discussed above do not specifically teach fish oil in the composition.

'367 claims in claim 1 a food supplement formulation of **fish oil** and lipase (the instant specification defines a fish oil to be intestinal mucosa function promoter). The supplement of '367 improves bodily functions including fat metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile. It would have been obvious to one of ordinary skill in the art to utilize fish oil in the teachings of primary references in order to improve fat metabolism motivated by the teachings of '367. It would have been further obvious to one of ordinary to substitute fish oil in the teachings of the references

discussed above because '999 teaches inclusion of omega fatty acids in the composition and fish oil is known in the art to comprise omega fatty acids as is evident by USP 6,608,223.

The teachings of combined references taught above do not disclose correlation of fish oil (intestinal mucosa function promoter) with lipid absorption or vitamin E absorption.

'007 teaches fish oil enhances absorption of vitamin E tocopherol and vitamin A, retinol and teaches lipid digestion and absorption in rat model, see example 2 in column 11 and 12, lines 60-68 and 1-5 respectively.

Additionally, WO '280 correlates the lipid absorption capacity with vitamin E absorption. As such, vitamin E absorption with the enhanced absorption of lipid in a pet animal would have been obvious to one of ordinary skill in the art by administration of a composition comprising fish oil, (an intestinal mucosa function promoter) and taurine, (a liver function promoter) in light of teachings of '367 and '619, '007 and further in view of WO '280, one would have expected improvement in vitamin E absorption.

A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Optimization of amounts would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

6. Claims 35, 45, 48-52 and 57-64 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al WO 02/15719 ('719) in view of (USP 6,524,619) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease, Proceedings ACVIM, Denver, CO, pp. 651-653, 2001, presented in IDS), (USP 6,228,367), (USP 6,610,007) and (W0 01/62280, presented in IDS).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein to improve, promote, maintain intestinal function and mucins a patient or **companion animal** (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21).

Example 4 teaches a nutritional supplement comprising whey protein and **probiotic bacteria**. (It is to be noted that probiotics are known to produce **lactic acid** and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism (pancreatic function promoter as claimed) provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). The amount of Whey

protein is taught to be 4.8% and vitamins and minerals to at least 5% of RDA in example 1 on page 13 , '719 also teaches including a probiotic (claim 13, pg. 5, lines 27-30). '719 teach including **taurine and** (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), (claimed as liver function promoter in instant claims). '719 teach a lipid source including **omega-3 fatty acids** (abstract, claim 1). (Claimed as intestinal function promoter in instant claims).

'719 teach a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2). The reference teaches various amounts of polyunsaturated fatty acids including omega 3 fatty acid to be 15 to 30%, see page 8, lines 10-20. The reference teaches vitamins (claimed as liver function promoter in instant application), see page 9, and lines 1-14.

The references disclosed above do not teach correlation of taurine with lipid absorption and correlation of lipid absorption with vitamin E levels.

"619 teaches taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001,

presented in IDS). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (See the entire articles of record).

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by '719 in order to help in lipid absorption motivated by the teachings of '619 and would expect improvement in vitamin E absorption in light of the teachings of Simpson et al. which teaches that vitamin E deficiency occurs due to defect in lipid absorption.

'719 does not teach fish oil (claimed as intestinal mucosa function promoter).

'367 claims in claim 1 a food supplement formulation of **fish oil and** lipase (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3) (abstract, claim 1). The supplement of '367 improves bodily functions including fat metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile. It would have been further obvious to one of ordinary to substitute fish oil in the teachings of the references discussed above because '999 teaches inclusion of omega fatty acids in the composition and fish oil is known in the art to comprise omega fatty acids as is evident by USP 6,608,223.

The teachings of combined references taught above do not disclose correlation of fish oil (intestinal mucosa function promoter) with lipid absorption or vitamin E absorption.

'0007 teaches fish oil enhances absorption of vitamin E tocopherol and vitamin A, retinol and teaches lipid digestion and absorption in rat model, see example 2 in column 11 and 12, lines 60-68 and 1-5 respectively.

Additionally, WO '280 correlates the lipid absorption capacity with vitamin E absorption. As such, vitamin E absorption with the enhanced absorption of lipid in a pet animal would have been obvious to one of ordinary skill in the art by administration of a composition comprising fish oil, (an intestinal mucosa function promoter) and taurine, (a liver function promoter) in light of teachings of '367, '619, '007 and further in view of WO '280, one would have expected improvement in vitamin E absorption.

A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Optimization of amounts would have been within the purview of a skilled artisan by doing experimental manipulations since the amounts depend on age, type of mammal, severity of vitamin deficiency, disease condition and condition of the mammal used, absent evidence to contrary.

Response to Arguments

7. Applicant's arguments with respect to claims 35, 45, 48-52 and 57-64 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612